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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,635	03/17/2006	Simon Nicholas Black	056291-5237	4207

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EXAMINER	
BALASUBRAMANIAN, VENKATARAMAN	
ART UNIT	PAPER NUMBER
1624	
MAIL DATE	DELIVERY MODE
11/06/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,635	BLACK ET AL.	
	Examiner	Art Unit	
	/Venkataraman Balasubramanian/	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 10-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 10-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response, which included cancellation of corrected claim 9 and amendment to claims 2, 3, 5, 6, 8 and 10-14, filed on 07/06/2009, is made of record. Claims 1-6 and 10-14 are now pending. In view of applicants' response, the 112 second and first paragraph rejections, claim objection and 101 rejection made in the previous office action have been obviated. However, the 102 rejection made in the previous office action is reapplied and a new ground of rejection is applied to currently pending claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Taylor et al., WO 01/60804 (equivalent US 6,841,554).

Taylor et al., teaches crystalline form of rosuvastatin with tris(hydroxymethyl)methylamine. See entire document. See page 3, entry 5, for crystalline form of tris(hydroxymethyl)methyl ammonium salt of rosuvastatin and pages 3-6, for details. See also page 4 lines 13-16. See examples 1-10 shown in pages 7-15.

This rejection is same as made in the previous office action but now excludes cancelled claim 9. Applicants' traversal to overcome this rejection by pointing out the difference between prior art crystal and instant forms 2 and 3 fully considered but

deemed as not persuasive. Applicants have not made direct comparison of instant crystal forms with that of Taylor. Taylor indicates that the figures shown and the position of specific peaks at theta 2 are not absolute and are likely to change. See page 4, last paragraph. In fact, such specific peaks vary from machine to machine and the way the X-ray powder diffraction is obtained. Applicants have not made a comparison under identical condition and shown that instant forms differs from that of Taylor in more than one characterization technique.

Furthermore, instant examples 1-2 shows same solvent used in Taylor and there appears to be no difference in the preparation of these two forms. In fact , solvents appear to be not critical for form 2. Taylor teaches, in page 5, the process of making which is same as used in the instant process. In fact , instant example 1 acknowledges it clearly. As for rejection of pharmaceutical composition claims 7-8, it should be noted that there is no showing that the form 2 and form 3 remain intact during the preparation of these pharmaceutical and in storage. As for rejection of method of use claim 10, there is no material difference between instant forms in terms of their structural make-up that contribute to their activity. There is no showing that specific peaks at theta 2, d-spacing and intensity of these peaks contribute to the method of treating. Taylor clearly teaches the method of use.

Hence, this rejection is proper and is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8 and 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al., WO 01/60804 (equivalent US 6,841,554).

Taylor et al., teaches crystalline form of rosuvastatin with tris(hydroxymethyl)methylamine. See entire document. See page 3, entry 5, for crystalline form of tris(hydroxymethyl)methyl ammonium salt of rosuvastatin and pages 3-6, for details. See also page 4 lines 13-16. See examples 1-10 shown in pages 7-15. See page 5 for details of the process of making. Note use suitable solvent such water, methanol, acetonitrile, ethyl acetate etc. are taught therein. Also see claims 6, 11, 12 and 15.

There is no direct comparison of instant crystal forms with that of Taylor. Taylor indicates that in the figures 1-9 shown, the position of specific peaks at theta 2 are not absolute and are likely to change. See page 4, last paragraph. In fact, such specific peaks vary from machine to machine and the way the X-ray powder diffraction is obtained. Applicants have not made a comparison under identical condition and shown that instant forms differs from that of Taylor in more than one characterization technique.

Furthermore, instant examples 1-2 shows same solvent used in Taylor and there appears to be no difference in the preparation of these two forms. In fact , solvents appear to be not critical for form 2. Taylor teaches, in page 5, the process of making

which is same as used in the instant process. In fact , instant example 1 acknowledges it clearly.

As for rejection of pharmaceutical composition claims 7-8, it should be noted that there is no showing that the form 2 and form 3 remain intact during the preparation of these pharmaceutical and in storage.

As for rejection of method of use claim 10, there is no material difference between instant forms in terms of their structural make-up that contribute to their activity. There is no showing that specific peaks at theta 2, d-spacing and intensity of these peaks contribute to the method of treating. Taylor clearly teaches the method of use.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1 and 7 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 6 and 11 of prior U.S. Patent No. 6,841,554. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-8 and 10-14 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 6, 11 and 12 of U.S. Patent No. 6,841,554. Although the conflicting claims are not identical, they are not patentably distinct from each other because the compound, the method of making and composition embraced in the instant claims are also claimed in the claims 6, 11 and 12 of US 6,841,554. See above 102 and 103 rejections. Hence, it would be obvious to one

trained in the art to make the compound and composition using the process taught in claim 12 and expect the crystalline form to have the use taught therein.

Conclusion

Any inquiry concerning this communication from the examiner should be addressed to Venkataraman Balasubramanian (Bala) whose telephone number is (571) 272-0662. The examiner can normally be reached on Monday through Thursday from 8.00 AM to 6.00 PM. The Supervisory Patent Examiner (SPE) of the art unit 1624 is James O. Wilson, whose telephone number is 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAG. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-2 17-9197 (toll-free).

/Venkataraman Balasubramanian/

Primary Examiner, Art Unit 1624